DEPARTMENT OF HEALTH AND HUM-AN SERVICE'S

DMB

Display Date 10-19-01 @ 4:12 pm
Publication Date 10-24-01
Certifier Medeiros

Food and Drug Administration

[Docket No. 0.1 N-04761

Electronic Interchange Standard for Digital ECG and Similar Data; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to collect information regarding the content and format of electrocardiographic (ECG) data to be submitted to the agency in support of applications. The agency is interested in obtaining ECG waveform data in digital format from the full spectrum of ECG devices (i.e., standard 12-lead ECGs, Holter monitors, transtelephonic monitors, and implanted devices) along with annotations for events (e.g., standard ECG interval measurements, arrhythmic events).

DATES: The public meeting will be held on November 19, 2001, from 10 a.m. to 4 p.m. Submit registration requests by November 6, 2001. Written or electronic comments on ECG data standards are welcome at any time.

ADDRESSES: The public meeting will be held at FDA's Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Norman L. Stockbridge, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5329, e-mail: stockbridgen@cder.fda.gov; or Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5400, e-mail: levinr@cder.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is holding a public meeting to discuss potential data standards for digital ECG waveform data to be submitted in support of applications to FDA. Topics

NM1

for discussion will include: (1) Scope of ECG datasets (i.e, what information should be included); (2) logical organization of a dataset supporting multiple recording sessions, multiple recording epochs within a session, and multiple leads; (3) logical organization supporting the annotation of data in one or more leads with the submitter's assessment of the locations of events of interest, including standard ECG intervals, at-rhythmic events, and other information; and (4) realization of the data in extensible markup language (XML) or other open formats.

Although the agency is considering updating guidance documents on related drug evaluation standards (i.e., arrhythmic potential, electronic submission of clinical trial data, including electronic ECG data), the use of ECG data in support of applications will not be the topic for this meeting. The purpose of this meeting is to get public input on the following questions related to the technical issues of transmitting digital ECG data:

- What information is needed to make ECG datasets easy to interpret?
- Is the data structure complex enough that the standard should be implemented in XML or some other format?
- Are the datasets so large that the data standards should be implemented in binary format?
- What tools can be used to review digital ECG data?

An agenda and other materials, including a proposed data standard, will be available on the Internet at http://www.fda.gov/cder/regulatory/ersr/default.htm before the meeting. Although there is no registration fee, preregistration by November 6, 2001, is recommended for those individuals who wish to attend this meeting. Participation is limited to the first 100 registrants. To accommodate the greatest number of interested parties, registration is limited to people outside FDA, and no more than two individuals from a company should attend. To register, send an e-mail message to Wendy Lail (lailw@cder.fda.gov) with the names of one or two individuals who wish to attend and the name of their company.

The location of the meeting is 5630 Fishers Lane, Rockville, MD (next to the Parklawn Bldg). Registrants should use the lower entrance, which faces Parklawn Dr. Visitors' badges will be held

at the guards' station at the entrance to the building, and participants will need picture identification to pick up their badges. Public parking is not available at the 5630 Fishers Lane location. A public parking lot (for a fee) is available on Fishers Lane across from the Parklawn Bldg. Additional public parking (for a fee) is available at the Twinbrook Metro Station, which is located several blocks west of the meeting location.

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments on standards for digital ECG data. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to http://www.fda.gov/dockets/

ecomments. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/19/01

October 19, 2001.

Margaret M. Dotzel

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL